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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,978	11/19/2004	Patrick Hwu	230591	4494

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EXAMINER	
DUFFY, BRADLEY	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/508,978	HWU ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8-22 and 25-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5,8-22 and 25-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a method of treating cancer in a mammal, comprising administering to a mammal an IL-21 polypeptide. The claim lacks inventive step over Ruben et al (WO 99/61617, published 12/02/1999, IDS filed September 24, 2004). Ruben et al teach administering IL-21 polypeptides to patients to treat hyperproliferative disorders, including neoplasms (see page 77). Therefore, claim 1 lacks an inventive step because it is anticipated by Ruben et al and the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 5, 18 and 22, drawn to a method of treating cancer in a mammal, comprising administering to a mammal an IL-21 polypeptide.

Group II, claims 2-4, 19-21, 39-41 and 48-50, drawn to a method of treating cancer in a mammal, comprising administering to a mammal an IL-21 polynucleotide.

Group III, claims 8, 11, 25 and 28, drawn to a method of treating cancer in a mammal, comprising administering to a mammal an IL-21 polypeptide and a viral vaccine.

Group IV, claims 8, 11, 25 and 28, drawn to a method of treating cancer in a mammal, comprising administering to a mammal an IL-21 polypeptide and a peptide vaccine.

Group V, claims 8, 13, 25 and 30, drawn to a method of treating cancer in a mammal, comprising administering to a mammal an IL-21 polypeptide and an antigen-specific T lymphocyte.

Group VI, claims 8, 12, 25 and 29, drawn to a method of treating cancer in a mammal, comprising administering to a mammal an IL-21 polypeptide and a cytokine.

Group VII, claims 9, 10, 26, 27, 42, 43, 51 and 52, drawn to a method of treating cancer in a mammal, comprising administering to a mammal an IL-21 polynucleotide and a viral vaccine.

Group VIII, claims 9, 10, 26, 27, 42, 43, 51 and 52, drawn to a method of treating cancer in a mammal, comprising administering to a mammal an IL-21 polynucleotide and a peptide vaccine.

Group IX, claims 9, 10, 26, 27, 46, 47, 55 and 56, drawn to a method of treating cancer in a mammal, comprising administering to a mammal an IL-21 polynucleotide and an antigen-specific T lymphocyte.

Group X, claims 9, 10, 26, 27, 44, 45, 53 and 54, drawn to a method of treating cancer in a mammal, comprising administering to a mammal an IL-21 polynucleotide and a cytokine.

Group XI, claim 14, drawn to a method of treating an immune-related disease in a mammal, comprising administering to a mammal an IL-21 polypeptide.

Group XII, claims 15-17, drawn to a method of treating an immune-related disease in a mammal, comprising administering to a mammal an IL-21 polynucleotide.

Group XIII, claim 31, drawn to a pharmaceutical composition comprising an IL-21 polypeptide.

Group XIV, claims 32-34, drawn to a pharmaceutical composition comprising an IL-21 polynucleotide.

Group XV, claims 35 and 36, drawn to a pharmaceutical composition comprising an IL-21 polypeptide and a viral vaccine.

Group XVI, claims 35 and 36, drawn to a pharmaceutical composition comprising an IL-21 polypeptide and a peptide vaccine.

Group XVII, claims 35 and 38, drawn to a pharmaceutical composition comprising an IL-21 polypeptide and an antigen-specific T lymphocyte.

Group XVIII, claims 35 and 37, drawn to a pharmaceutical composition comprising an IL-21 polypeptide and a cytokine.

Group XIX, claim 57, drawn to a pharmaceutical composition comprising an IL-21 polynucleotide and a vaccine.

Group XX, claim 57, drawn to a pharmaceutical composition comprising an IL-21 polynucleotide and an antigen-specific T lymphocyte.

Group XXI, claim 57, drawn to a pharmaceutical composition comprising an IL-21 polynucleotide and a cytokine.

Group XXII, claim 58, drawn to a method of inducing apoptosis of a natural killer cell by contacting the NK cell with an IL-21 polypeptide.

Group XXIII, claim 59, drawn to a method of inducing apoptosis of a natural killer cell by contacting the NK cell with an IL-21 polynucleotide.

Group XXIV, claims 60-62, drawn to a method of activating natural killer cell cytolytic activity by contacting the NK cell with an IL-21 polypeptide.

Group XXV, claims 63-65, drawn to a method of activating natural killer cell cytolytic activity by contacting the NK cell with an IL-21 polynucleotide.

3. The inventions listed as Groups I-XXV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, Claim 1 lacks inventive step over Ruben et al. Therefore, the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

The inventions are independent or distinct, each from the other because:

The methods of Inventions of Groups I-II, Groups XI-XII, Groups XXII-XXIII and Groups XXIV-XXV differ in the method objectives and method parameters. The method

of Groups I-II recites treating a mammal with cancer. The method of Groups VII-X recites treating a mammal with an immune-related disease. The method of Groups XXII-XXIII recites inducing apoptosis in NK cells. The method of Groups XXIV-XXV recites activating NK cell cytolytic activity.

The methods of Inventions of Groups (I and III-VI), Groups (II and VII-X), Groups (XXII-XXIII) and Groups (XXIV-XXV) differ in the method steps, parameters and in the reagents used. The invention of Group I recites a method of treating cancer by administering an IL-21 polypeptide. The invention of Group III recites a method of treating cancer by administering an IL-21 polypeptide and a viral vaccine. The invention of Group IV recites a method of treating cancer by administering an IL-21 polypeptide and a peptide vaccine. The invention of Group V recites a method of treating cancer by administering an IL-21 polypeptide and an antigen-specific T lymphocyte. The invention of Group VI recites a method of treating cancer by administering an IL-21 polypeptide and a cytokine. The invention of Group II recites a method of treating cancer by administering an IL-21 polypeptide. The invention of Group VII recites a method of treating cancer by administering an IL-21 polynucleotide and a viral vaccine. The invention of Group VIII recites a method of treating cancer by administering an IL-21 polynucleotide and a peptide vaccine. The invention of Group IX recites a method of treating cancer by administering an IL-21 polynucleotide and an antigen-specific T lymphocyte. The invention of Group X recites a method of treating cancer by administering an IL-21 polynucleotide and a cytokine. The invention of Group XXII recites inducing apoptosis in NK cells by treating with IL-21 polypeptide. The

invention of Group XXIII recites inducing apoptosis in NK cells by treating with IL-21 polynucleotide. The invention of Group XXIV recites activating NK cell cytolytic activity by treating with IL-21 polypeptide. The invention of Group XXV recites activating NK cell cytolytic activity by treating with IL-21 polynucleotide. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups (I and III-VI), Groups (II and VII-X), Groups (XXII-XXIII) and Groups (XXIV-XXV) are patentably distinct.

Inventions of Groups (XIII and XV-XVIII) and Groups (XIV and XIX-XXI) represent separate and distinct products, which are made by materially different methods, and are used in materially different methods. The polynucleotides of (XIV and XIX-XXI) and the polypeptides of Groups (XIII and XV-XVIII) are all structurally and chemically different from each other. A polynucleotide's structure is comprised of linear, contiguous nucleotides, while a polypeptides's structure is comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure. The polypeptide is made by translation of mRNA, while the polynucleotide is made by nucleic acid synthesis. Furthermore, the polypeptide can be used for methods of treatment, while the polynucleotide can be used for hybridization screening. Finally, Groups (XIII and XV-XVIII) and Groups (XIV and XIX-XXI) are distinct from each other as they require distinct structural and functional elements that are not disclosed as used one for the other. For example, a viral vaccine is comprised of viral particles, a peptide vaccine is comprised of peptide antigens, T lymphocytes are comprised of cells and

cytokine are comprised of functional polypeptides. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups (XIII and XV-XVIII) and Groups (XIV and XIX-XXI) are patentably distinct.

Inventions of Groups (XIII and XV-XVIII) and (I and III-VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the IL-21 polypeptide of Groups (XIII and XV-XVIII) could be used in the materially different process of producing antibodies, which differs in the method objective, method steps, parameters, reagents used and endpoint from the process of treating cancer of Groups (I and III-VI) and are therefore distinct.

Inventions of Groups (XIV and XIX-XXI) and (II and VII-X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the IL-21 polynucleotides of Groups (XIV and XIX-XXI) could be used in the materially different process of producing IL-21 protein, which differs in the method objective, method steps, parameters, reagents used and endpoint from the process of treating cancer of Groups (II and VII-X) and are therefore distinct.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

David Blanchard
AU 1643